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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,395	12/27/2000	Thomas Specht	SCH-1780	6808

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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,395	SPECHT ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-22,28,29 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-27 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, Claims 23-27, 30-32 in Paper No. 10 is acknowledged. Applicant's argue that the examiner has not established an undue searching burden. It is noted that this application is a 371 application which is subject to lack of unity practice. Lack of unity practice does not require a showing of undue burden. Therefore, the argument is not found persuasive.

As noted in the interview summary form of June 20, 2002, applicants intended to elected the polypeptides of Group III, Claims 23-32. Moreover, the examiner also noticed that Claims 28-29 were not drawn to the polypeptides and therefore should properly be placed in Group I.

Prior to allowance, non-elected subject matter must be cancelled from the claims.

Claim Objections

2. Claims 24, 26 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 24 and 26 depend from Claim 23. Claim 23 is directed to a polypeptide partial sequence according to SEQ ID NO: 238. This claim appears to require each of the positions from within SEQ ID NO: 238 without any variability. Claims 24 and 26 are broader in scope than the single SEQ ID NO: 238.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 27, 30-31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-27, 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using polypeptides of SEQ ID NO: 238, does not reasonably provide enablement for polypeptides which are 80%, 90% or partial SEQ ID NO: 238 sequences. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches numerous genes and their expression patterns in different tissues as compared to cancerous tissues. The gene product of SEQ ID NO: 33, which encodes the polypeptide of SEQ ID NO: 238 is expressed 39 times more frequently in cancerous tissue as compared to normal uterus-endometrial tissue.

The art does not teach how to use polypeptides which are 80%, 90% or partial polypeptide sequences of SEQ ID NO: 238.

Neither the specification nor the art teach the skilled artisan how to use the invention as broadly as claimed. The specification nor the art teaches the skilled artisan how to use the polypeptides which are 80% or 90% identical with SEQ ID NO: 238. While the specification teaches that SEQ ID NO: 238 is overexpressed in uterus-endometrium cancer tissue as compared with normal tissue, the specification does not teach how to use sequences which are similar to SEQ ID NO: 238. The skilled artisan would be required to perform undue experimentation on the variant SEQ ID NO: 238 to determine whether the variant sequences are also overexpressed in the cancerous tissue or whether the sequences are found only in normal tissue. Similarly, the specification does not teach how to use partial sequences from SEQ ID NO: 238 because it is unclear whether these partial sequences are specific to the polypeptide.

5. Claims 30-32 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to pharmaceutical agents comprising polypeptide partial sequence SEQ ID NO: 238 or the "use" of the polypeptide as pharmaceutical agents.

The pharmaceutical composition claims are not enabled for use because the language "pharmaceutical" implies that the polypeptide of the claims provides for in vivo applicability particularly for treatment, but such is not enabled.

The specification teaches numerous genes and their expression patterns in different tissues as compared to cancerous tissues. The gene product of SEQ ID NO: 33, which encodes the polypeptide of SEQ ID NO: 238 is expressed 39 times more frequently in cancerous tissue as compared to normal uterus-endometrial tissue. The specification does not provide any studies either in vitro or in vivo which illustrate any therapeutic or pharmaceutical use. The state of the art in therapeutics is not clear-cut, and does not allow for results absent any in vivo studies. The specification has not provided any in vitro studies. Therefore, absent any analysis of the polypeptide in vivo, the skilled artisan would not be able to use the polypeptide as a therapeutic absent undue experimentation. The specification provides not guidance to using the polypeptide as a pharmaceutical compound. The polypeptide could not be used for treatment of some disease or condition in vivo without undue experimentation.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-27, 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptide which are 80% or 90% or bind to a partial polypeptide of SEQ ID NO: 238.

The specification teaches SEQ ID NO: 238 is expressed 39 times more frequently in cancerous uterus-endometrium tissue as compared to normal tissue. SEQ ID NO: 238 is 108 amino acids in length.

Depending on how the claim language is intended to read, Claim 23 lacks adequate description for a partial sequence of SEQ ID NO: 238 which is embedded within a larger polypeptide sequence. The specification fails to describe a portion of SEQ ID NO: 238 embedded within a larger polypepetide. Moreover, the specification does not appear to teach a full protein, therefore, a claims to a polypeptide comprising the partial polypeptide sequence reads upon a full protein which has not been described. The partial polypeptide sequence does not begin with a start codon, therefore, the partial polypeptide sequence does not appear to be a full protein.

With respect to Claims 25, the specification fails to describe a polypeptide which can bind to SEQ ID NO: 238 or a partial sequence thereof. There is no indication of which sequences would bind to the SEQ ID NO: 238. Moreover, if the polypeptide is known as required by the claim, the claim would be anticipated.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23-27, 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 23-26 are indefinite because it is unclear whether the claims are directed to polypeptide partial sequences comprising SEQ ID NO: 238 or whether the claim is directed to the partial sequence consisting of SEQ ID NO: 238 or whether the claim is directed to fragments of SEQ ID NO: 238 which are partial polypeptide sequences. The term "according to SEQ ID NO: 238" does not make either of the alternatives more likely. Applicant's are requested to clarify.

B) Claims 27, 30-31 provides for the use of polypeptide partial sequences, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

C) Claim 30 is indefinite because it is unclear how one may use a polypeptide as an agent in gene therapy. Gene therapy can be defined as the introduction of a gene into a cell for the purpose of correcting a hereditary disease or improving the genome.

The definition of gene therapy implies that genes, not polypeptides are used for the therapy. Therefore, it is unclear how the polypeptide is used for gene therapy.

D) Claim 32 is indefinite because it is unclear whether the pharmaceutical agent comprises a polypeptide sequence of SEQ ID NO: 238, or whether the composition comprises a partial sequence from SEQ ID NO: 238 or whether the composition consists of SEQ ID NO: 238 or a partial sequence from SEQ ID NO: 238. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 23-24, 26-27, 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US Pat. 6,174,992, January 2001).

Ni et al. (herein referred to as Ni) teaches a hESF III polypeptide sequence, namely SEQ ID NO: 6, which is 100% identical to amino acid positions 14-108 of the instant application's SEQ ID NO: 238.

Therefore, hESF III, SEQ ID NO: 6 of Ni is a polypeptide partial sequence of SEQ ID NO: 238 (limitations of Claim 23). The polypeptide of Ni is 100% identical to positions 14-108 of the partial sequence of SEQ ID NO: 238 (limitations of Claims 24, 26). The intended use of the partial polypeptide sequences does not carry any patentable weight such that the polypeptide product differs (limitations of Claims 27, 30-31). The pharmaceutical composition claim, Claim 32, is directed to a composition, because the pharmaceutical language recited in the claims does not impart any particular or new feature, this is interpreted as an "intended use".

9. Claims 23-24, 26-27, 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ni et al. (WO 97/34997, September 1997).

Ni et al. (herein referred to as Ni) teaches a hESF III polypeptide sequence, namely SEQ ID NO: 6, which is 100% identical to amino acid positions 14-108 of the instant application's SEQ ID NO: 238.

Therefore, hESF III, SEQ ID NO: 6 of Ni is a polypeptide partial sequence of SEQ ID NO: 238 (limitations of Claim 23). The polypeptide of Ni is 100% identical to positions 14-108 of the partial sequence of SEQ ID NO: 238 (limitations of Claims 24, 26). The intended use of the partial polypeptide sequences does not carry any patentable weight such that the polypeptide product differs (limitations of Claims 27, 30-

31). The pharmaceutical composition claim, Claim 32, is directed to a composition, because the pharmaceutical language recited in the claims does not impart any particular or new feature, this is interpreted as an "intended use".

Conclusion

10. No claims allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg J. Goldberg
July 10, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600